REMARKS

By this amendment, Applicants have amended claim 1:

1) to recite that hair treatment shampoos are rinse-off shampoos (page 5, line 7) applied to the hair for about 30 seconds prior to rinsing (page 28, lines 22-23); and
2) to incorporate the language of previously presented claim 4 (relating to minimum number of hydroxyl and/or amine groups and proximity of groups to one another) into the claim.

As will be discussed in more detail below, the recitation of hydroxyl and/or amino groups and their proximity to one another is the emphasize the selection nature of the invention compared to potential hundreds or more molecules which do not meet these limitations but which are perfectly adequate for use in U.S. Publication No. 2004/0067209 to Brown (hereinafter "Brown"). Further, recitation of "rinse-off" shampoo applied to hair for about 30 seconds is to highlight that the topical, dermatological composition of Brown (applied as ointment, lotion or, theoretically, topical shampoos) are completely different from rinse-off shampoo cleansers contemplated by the subject invention.

In addition, applicants have cancelled claims 4 and 9. Accordingly, claims now pending in the subject application are claims 1-3, 5-7 and 10 as currently amended.

At page 2-3 of the Office Action, the Examiner has rejected claim 9 under 35 USC §112, Second Paragraph. Without responding to the merits of this rejection, applicants have cancelled, without prejudice, claim 9 from the claims. Accordingly, it is respectfully requested that the rejection under 35 USC §112 be withdrawn.

At page 3 of the Office Action, the Examiner has rejected claims of the subject application under 35 USC §103(a) as allegedly unpatentable over Brown in view of WO 00/00164 to Michael (hereinafter "Michael"). Brown is said to teach preferred ingredient butanediol (¶0172 and Table 5 at page 7); as well as application of composition and methods in formulations such as shampoo. While recognizing that Brown does not teach composition with claimed surfactants, the Examiner recites compositions of Michael to remedy this deficiency. This rejection is respectfully traversed for reasons set forth below.

Initially, applicants note that the invention is at its heart a patent of selection. Specifically, applicants have identified very specific branched amine and/or hydroxy compounds which, quite unpredictably, have been found to repair and prevent principal symptoms of damaged hair (page 2, lines 21-24 of specification). As amended, the compounds (1) must comprise at least two hydroxyl groups, amino groups or mixtures thereof; and (2) must have total number of carbon atoms in the molecule such that each OH or NH_2 is positioned with 0.5 n or less carbon (n being total number of carbons in the molecule) directly between it and all other OH or NH_2 groups.

It is only when these specific conditions are satisfied that the hair cuticles showed unexpectedly superior recovery (see Example 1 at pages 28-30 and particularly the

Table at the bottom of page 29). Moreover, the molecule is applied from a rinse-off shampoo composition which is typically applied for about 30 seconds before rinsing. It should be noted that the language relating to "about 30 seconds" is primarily added to distinguish typical rinse-off shampoos from a topical shampoo where, typically, since there is some form of medicament which is meant to be absorbed on skin or hair, the shampoo is lathered onto substrate for 4 or 5 minutes or more. Thus, it should be noted that, in a rinse shampoo, the user can still lather for 1 or 2 minutes and, again, the 30 second claim language is just a guide as to how a rinse-off shampoo (versus "topical" shampoo) is typically used.

Regarding US '209 to Brown et al., the selective nature of the compounds of our invention is completely unappreciated. Thus, although it is true that butanediol compounds similar to those of our invention may be used, there are also many, many components disclosed (which may provide melanin-enhancing benefit desired by Brown) which would have no benefit as hair cuticle recovery molecules. For example, ¶0077 discloses 2,4-pentanediol compound, which molecule is similar to the inferior comparative molecule discloses as component B at page 28.

Further, as noted, as defined at ¶0023-0029, there is no requirement that the molecules necessarily have hydroxyl or amine groups. In all cases X, R_1, R_2 or R may be oxygen or sulfur or straight alkyl and may never have hydroxyl or amine (e.g., camphene of ¶0120, bornane of ¶0154, or many other compounds disclosed at pages 3-5). Further, even among the diols, there appear to be many compounds which fail to meet the test of being 0.5 n or less between all other OH or NH_2 groups (e.g., 1,10 decanediol; 1,14 tetradecanediol; 1,16 hexadecanediol).

In short, the reference simply fails to recognize the criticality which the molecules of our invention, as we have clearly demonstrated, must possess.

In addition, it is clear that the compositions of Brown are intended to be left on the skin as topical compositions. Typically, these compositions would include ointments, lotions, pastes, etc. (¶0173); and the molecules are intended to be left on and not washed off the skin. Thus, although the term "shampoo" is used, this refers to topical shampoos where medicaments are intended to be left on the substrate for 4 or 5 minutes rather than the rinse-off shampoos typical of cleanser shampoo formulations.

In this regard, applicants enclose copies of web pages (from MedicineNet.com) relating to Lindane topical shampoos (intended to treat lice) and web pages related to Capex Shampoo (intended as anti-inflammatory). As seen at page 2 of the Lindane Shampoo pages or page 4 of the Capex Shampoo pages, these topical shampoos are intended to be left on for 4 or 5 minutes. As noted, applicants' claims are directed to rinse-off shampoo which are typically applied to hair for much shorter time (although claim language recites about 30 seconds, it should be understood that this depends on the user and can be applied for two minutes or more).

Michael et al. does nothing to cure the deficiency of the primary Brown reference.

In view of the amended and arguments above, it is respectfully requested that the Examiner reconsider and withdraw the rejection of claims.

With regard to the rejection of Brown in view of Patel at page 5, the arguments are exactly the same. Again, the primary Brown reference fails for reasons discussed above; and the Patel reference does nothing to cure this deficiency.

In view of the above, it is respectfully requested that the Examiner withdraw all rejections of the claims and these claims, as amended, be allowed.

If a telephone conversation would be of assistance in advancing the prosecution of the present application, applicants' undersigned attorney invites the Examiner to telephone at the number provided.

Respectfully submitted,

Ronald A. Koatz RAK

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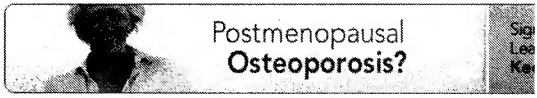

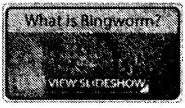

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GENERIC NAME: LINDANE - TOPICAL SHAMPOO (LINN-dane)

WARNING: Lindane should only be used after safer medications have failed, or if safer medications caused side effects. Infrequently, lindane has caused seizures (and sometimes death) after prolonged or repeated use. Rare (sometimes fatal) nervous system reactions such as seizures may even occur after correct one-time use of lindane Lindane should not be used in premature infants or those with poorly-controlled seizure disorders. Lindane should be used with caution in infants, children, the elderly, those wit other skin conditions (such as dermatitis or psoriasis), and those who weigh less than 1' pounds (50 kg) as they may be at a higher risk for side effects. Read the patient instructi sheet and Medication Guide before use, and ask your doctor or pharmacist about any information that is unclear to you. Itching may occur either after successful treatment or with treatment failures. Avoid re-applying lindane within a few months after use.

USES: This medication is used to treat head and crab (pubic) lice after safer medication have failed, or if safer medications caused side effects. It works by killing the lice and th eggs (nits).

HOW TO USE: Be sure to learn all the instructions for use from your doctor or pharmaci and read the instruction sheet and Medication Guide carefully before using this medication. Wash hair with your regular shampoo (without conditioner) and dry your hai well. Wait at least one hour before using the lindane shampoo to lessen the chance of absorbing the lindane through your skin. Shake the medication well before using. Wear

disposable gloves (made of nitrile, latex with neoprene, or sheer vinyl) when applying thi medication. Do not use natural latex gloves because more lindane can penetrate that ty of glove. Do not apply to eyes, mucous membranes (e.g., inside of the nose or mouth) a do not take by mouth. If lindane gets in the eyes, rinse eyes immediately with water and seek immediate medical attention if a burning sensation continues. Apply the medicatior dry hair without using water. Work it in well (without lathering) and leave it in hair for exactly four minutes (use a timer or clock). After four minutes add a little warm water unt shampoo lathers well. Do not use hot water. Rinse off the shampoo immediately after it lathers. Dry hair with a towel and remove nits (eggs) from hair with a nit comb or tweeze Wash your hands when you are done. Discard gloves and lindane container into the tras out of the reach of children and pets. All recently worn clothing, underwear, pajamas, bedsheets, pillows, towels, and stuffed animals should be washed in very hot water or d cleaned. Do not use lindane shampoo again without checking with your doctor.

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Suggested Reading by Our Doctors

- Head Lice Infestation (Pediculosis) - Get the facts on head lice (pediculosis) infection symptoms, signs, prevention, treatment and information on home remedies, and learn what head lice (and nits) look like.

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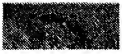

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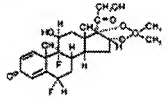
Capex® Shampoo (fluocinolone acetonide)
Topical Shampoo, 0.01%

Rx Only
For Dermatological Use Only
Not for Ophthalmic Use
NDC 0299-5500-04

DESCRIPTION: Capex® Shampoo 0.01% is supplied as a shampoo formulation with a 12 mg fluocinolone acetonide capsule which is emptied into the shampoo base by the pharmacist at the time of dispensing. After mixing, Capex® Shampoo contains fluocinolone acetonide (6α, 9-Difluro-11β, 16α, 17,21 -tetrahydroxypregna-1,4-diene-3, 20-dione cyclic 16,17-acetal with acetone), a synthetic fluorinated corticosteroid for topical dermatologic use. The corticosteroids constitute a class of primarily synthetic steroids used topically as an anti-inflammatory and antipruritic agents.

Chemically, Capex® Shampoo mixture is $C_{24}H_{30}F_2O_5$.
It has the following structural formula:



Fluocinolone acetonide in Capex® Shampoo has the molecular weight of 452.50. It is a white crystalline powder that is odorless, stable in light and melts at 270°F with decomposition; soluble in alcohol, acetone and methanol; slightly soluble in chloroform; insoluble in water.

Each fluocinolone capsule contains 12 mg of fluocinolone acetonide, 548 mg of dibasic calcium phosphate dihydrate USP, and 240 mg of talc USP. The shampoo base contains aluminum acetate basic, benzalkonium chloride solution, boric acid, citric acid anhydrous, cocamido-ether-sulfate complex, cocoamine oxide, lauramide DEA, magnesium aluminum silicate, methylparaben, oat flour, propylene glycol, propylparaben, purified water, and fragrances, with D&C Yellow #10 and FD&C Blue #1 as coloring.

CLINICAL PHARMACOLOGY: Like other topical corticosteroids, fluocinolone acetonide has anti-inflammatory, antipruritic and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Occlusive dressings with hydrocortisone for up to 24 hours have not been demonstrated to

increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin while inflammation and/or other disease processes in the skin increase percutaneous absorption.

Capex® Shampoo is in the low- to medium-potency as compared with other topical corticosteroids.

CLINICAL STUDIES: In vehicle-controlled studies for the treatment of Seborrheic Dermatitis of the scalp, after 14 days of treatment, 84% of patients on active treatment and 29% of patients on the drug vehicle had cleared or markedly improved.

INDICATION AND USAGE: Capex® Shampoo is a low- to medium-potency corticosteroid indicated for the treatment of Seborrheic Dermatitis of the scalp. This product has not been proven to be effective in other corticosteroid-responsive dermatoses.

CONTRAINDICATIONS: Capex® Shampoo is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS: General: Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticoid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, A.M. plasma cortisol, and urinary free cortisol tests. Patients receiving superpotent corticosteroids should not be treated for more than 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA suppression.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Infrequently, signs and symptoms of glucocorticoid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. (See PRECAUTIONS — Pediatric Use).

If irritation develops, Capex® Shampoo should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by a *failure to heal* rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of Capex® Shampoo should be discontinued until the infection has been adequately controlled.

Information for Patients: Patients using topical corticosteroids should

receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes. In case of contact, wash eyes liberally with water.

2. This medication should not be used for any disorder other than that for which it was prescribed.

3. The treated scalp area should not be bandaged or otherwise covered or wrapped so as to be occlusive unless directed by the physician.

4. Patients should report to their physician any signs of local adverse reactions.

5. Discard contents after three (3) months.

Laboratory Tests: The following tests may be helpful in evaluating patients for HPA axis suppression.

- ACTH stimulation test
- A.M. plasma cortisol test
- Urinary free cortisol test

Carcinogenesis, mutagenesis, and impairment of fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of Capex® Shampoo.

Pregnancy: Teratogenic effects: Pregnancy category C: Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

There are no adequate and well-controlled studies in pregnant women or teratogenic effects from Capex® Shampoo. Therefore, Capex® Shampoo should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are secreted in human milk, caution should be exercised when Capex® Shampoo is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children and infants have not been established. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression when they are treated with topical corticosteroids. They are therefore also at a greater risk of glucocorticoid insufficiency after withdrawal of treatment and of Cushing's syndrome while on treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children.

HPA axis suppression, Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth

retardation, delayed weight gain, low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches and bilateral papilledema.

ADVERSE REACTIONS: The following local adverse reactions have been reported infrequently with topical corticosteroids. They may occur more frequently with the use of occlusive dressings, especially with higher potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: dryness, folliculitis, acneiform eruptions, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, miliaria, burning, itching, irritation, and hypopigmentation.

OVERDOSAGE: Topically applied Capex® Shampoo can be absorbed in sufficient amounts to produce systemic effects (See PRECAUTIONS).

DOSAGE AND ADMINISTRATION: The pharmacist must empty the contents of the enclosed capsule into the shampoo base prior to dispensing to the patient. This product should be shaken well prior to use. No more than approximately one (1) ounce of the medicated shampoo should be applied to the scalp area once daily, worked into a lather, and allowed to remain on the scalp for approximately 5 minutes. The hair and scalp should then be rinsed thoroughly with water.

HOW SUPPLIED: Capex® Shampoo is supplied as a two component package: a capsule which contains the active component fluocinolone acetonide 0.01%, and a separate package of liquid shampoo. The pharmacist must mix the content of the capsule into the base at the time of dispensing. Capex® Shampoo is dispensed to the patient in a 6 ounce bottle.

Shake well before using.

Store between 15° and 30° C (59° and 86° F) in tightly closed containers.